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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MAYER, BROWN, ROWE & MAW LLP
1909 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER	
LUSTUSKY, SARA	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,036	DAVIS ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-16,18-21 and 23-39* is/are rejected.

7)☒ Claim(s) *9 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/936687.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The Examiner acknowledges Applicant's Amendment dated January 12, 2007. Claims 10-11, 23-24 and 36-37 are amended. Claim 17 has been canceled. Claims 1-16 and 18-39 are pending.

Claim Rejections - 35 USC § 112

In Applicant's Amendment dated January 12, 2007 on page 7, Applicant states that claims 33-35 have been amended to correct the informalities identified in the claim rejections under 35 USC 112, second paragraph as set forth in the Office Action dated September 19, 2006. However, claims 33-35 have not been amended in the documents dated January 12, 2007, not are they indicated as being amended. Therefore, these claims remain rejected as follows.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 34 recite the limitation "the computer readable medium" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 35 recites the limitation "the computer readable medium" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 12-16, 18-21, 23 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sony (TCD-D8 1995).

Sony teaches a device comprising a computer readable medium for storing a desired signal (as described on pages 2, 28-29 and 35), an output for outputting the signal to the auditory system, and a volume-adjusting feature (described on pages 18 and 37); wherein the device is capable of being used to treat an auditory system disorder, including tinnitus and hyperacusis, and wherein the patient may reset the volume at any time; wherein the device includes a compliance monitoring device (as described on page 40), a battery (as described on page 25); wherein the battery life may last for at least one week of treatment depending on the length of use of the device during the treatment (as described on page 25); wherein the computer readable medium has a storage capacity sufficient to provide a choice, range, or diversity of treatment signals (as described on pages 2, 28 and 29); wherein the computer readable medium storage capacity is approximately equivalent to 4 hours (as described on page 35); wherein the device further comprises coding of the treatment signal capable of preventing copying and tampering by a user (as described on page 29); wherein the device comprises a data downloading function, performed by a wired interface, capable

of downloading logged information (for example: preferred treatment signals) which relate to the patient's use of the device (as described on page 28).

Claims 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gooch (Patent 5403262).

Gooch teaches a device comprising signal filtering means configured to generate a treatment signal with peaks and troughs (as seen in Figures 9-12), an output for outputting the signal (as seen in Figures 3 and 4), and a volume adjusting feature (as described in lines 48-64 of column 4; in lines 24-45 of column 5; and in lines 55-66 of column 7); wherein the signal filtering means filter an input signal as required to treat a user and is therefore capable of treating hyperacusis; wherein the effectiveness of the treatment signal depends on the individual patient during each peak and trough; wherein the device further comprises a compliance monitoring device which allows a specified or predetermined time interval for a given treatment session to be selected with a timer selector (as described in lines 57-63 of column 5).

Claims 27-29, 31-32 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Adleman (Patent 6041129).

Adleman teaches a device comprising a signal filtering means configured to generate a treatment signal with peaks and troughs by modification of an input signal, an output for outputting the signal, a volume adjusting feature, a battery for supplying power to the device wherein the battery life may be equivalent to at least one week of treatment depending on the treatment regime; wherein the device further comprises a data downloading function capable of downloading logged information wherein the data

downloading function is performed by a wired or wireless interface (as described in lines 41-44 of column 6, lines 62-64 of column 14; in lines 36-48 and 62-67 of column 16, and lines 1-60 of column 17).

Claims 27-29, 31-32 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Topholm (Patent 4947432).

Topholm teaches a device comprising a signal filtering means, an output, a volume adjusting feature capable of being used for requiring a patient to reset the volume of a treatment signal, a coding of the treatment signal and a patient identification code which serve as a locking function, and a battery which serves to supply the device with power and wherein the life of the battery may provide at least one week of treatment depending on the treatment regime (as described in lines 37-42 of column 2, lines 30-33 of column 3, lines 9-18 of column 4, lines 10-17 of column 5, and in lines 59-60 of column 6); wherein the signal filtering means filter an input signal as required to treat a user and is therefore capable of treating hyperacusis; wherein the effectiveness of the treatment signal depends on the individual patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10, 14-16, 18-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Jassim (1988) in view of Sony (TCD-D8 1995).

Al-Jassim teaches a device for providing treatment of an auditory system disorder comprising: a computer readable medium for storing a treatment signal, an output for the treatment signal; wherein the device may be used to treat tinnitus or hyperacusis; wherein the treatment signal may be a highly dynamic masking signal whose spectral content and intensity constantly varies over time (as described in paragraph 4 of column 1 of page 27; and in paragraph 1 of the Discussion on page 27). While Al-Jassim teaches that an auditory disorder may be treated by using a Walkman, the specific type of Walkman is not disclosed.

Sony teaches a device, known as a Walkman, comprising a computer readable medium for storing a desired signal (as described on pages 2, 28-29 and 35), an output for outputting the signal to the auditory system, and a volume-adjusting feature (described on pages 18 and 37); wherein the device is capable of being used to treat an auditory system disorder, including tinnitus and hyperacusis, and wherein the patient may reset the volume at any time; wherein the device includes a compliance monitoring device (as described on page 40), a battery (as described on page 25); wherein the battery life may last for at least one week of treatment depending on the length of use of the device during the treatment (as described on page 25); wherein the computer readable medium has a storage capacity sufficient to provide a choice, range, or diversity of treatment signals (as described on pages 2, 28 and 29); wherein the computer readable medium storage capacity is approximately equivalent to 4 hours (as

described on page 35); wherein the device further comprises coding of the treatment signal capable of preventing copying and tampering by a user (as described on page 29); wherein the device comprises a data downloading function, performed by a wired interface, capable of downloading logged information (for example: preferred treatment signals) which relate to the patient's use of the device (as described on page 28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a Walkman similar to that of Sony to administer a treatment signal in a method similar to that taught by Al-Jassim to treat an auditory disorder because the Walkman is less expensive than commonly used tinnitus maskers, is readily usable which cuts down on the caregiver's time as well as the user's wait time for receiving treatment, the device is easy to handle and allows the user to choose from a variety of treatment signals (as described in column 1 of page 28 of Al-Jassim).

Claims 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sony (TCD-D8 1995) in view of Wolf et al. (Patent 4254922).

Sony teaches the device of claim 14, comprising a computer readable medium, an output, and a volume-adjusting feature for outputting a treatment signal, as described above, but does not teach a patient identification code.

Wolf et al. teaches a device comprising a computer readable medium and an output wherein the device further comprises a locking mechanism and an identification code (as described in claims 1, 24 and 25 and in lines 16-20 of column 9) (as seen in Figure 17).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a device similar to that of Sony with an identification code similar to that of the device of Wolf et al. in order to identify the owner of said device if lost.

Claims 27-29, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zoels et al. (Patent 6047074) in view of Rastatter et al. (Patent 5961443).

Zoels et al. teaches a device comprising a signal filtering means configured to generate a treatment signal with peaks and troughs by modifying an input signal and an output for outputting the signal for treatment of an auditory disorder, including tinnitus; wherein the signal filtering means and output are part of a hearing aid (as described in the abstract and in lines 36-67 of column 2 and lines 1-16 of column 3). Zoels et al. however, does not expressly teach a hearing aid with a volume-adjusting feature.

Rastatter et al. teaches a hearing aid (10) with a volume adjusting feature (15a) for treatment of an auditory disorder (as seen in Figure 1); wherein the hearing aid further comprises a battery (as described in lines 58-67 of column 4; lines 63-67 of column 8 and lines 1-4 of column 9) and/or a battery pack which supplies power for extended use which could last for a week, depending on the treatment regime.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a hearing aid similar to that of Rastatter et al. with a signal filtering means similar to that taught by Zoels et al. to produce an output for treating an auditory disorder because the hearing aid of Rastatter et al. is designed to provide a user with a therapeutic signal and the volume adjust allows for increased comfort of the user.

Allowable Subject Matter

Claims 9 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 9 and 22, none of the prior art of record teaches or fairly suggests a device for providing treatment of an auditory system disorder comprising, a computer readable medium, an output for outputting the signal for treating the auditory system disorder, a volume adjusting feature and a safety locking function capable of preventing a patient from using the device if the computer readable medium does not contain the patient's treatment signal.

Response to Arguments

Applicant's arguments dated January 12, 2007 on page 7 with respect to claims 1-8, 10, 12-21, 23, 25 and 26 as rejected under 35 USC 102(b) over Song (TCD-D8 1995) have been fully considered but they are not persuasive. Applicant contends that Song does not recite all the claim limitations as set forth in claim 1, stating that Song does not teach a device for providing treatment of an auditory system disorder or a computer readable medium for storing a treatment signal or a volume adjusting feature for requiring a patient to reset the volume of the treatment signal. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than

function. The device of Sony (1995) includes all the structural limitations in these claims and is fully capable of being used for providing treatment of an auditory system disorder and has a volume adjust feature where a patient may adjust the volume at any time including at the beginning of a treatment session if required. The recitation for requiring a patient to reset the volume is considered to be intended use. Regarding claim 14, the note on page 40 of Sony (1995) merely states to the user that the display does not indicate the time of day (for example: 6:00 pm), but it does indicate an amount of time a user has been using the device. By merely indicating an intended use of the invention, the Applicant has failed to structurally distinguish the apparatus as claimed from the prior art of record.

Applicant's arguments dated January 12, 2007 on page 8 with respect to claims 27-30 as rejected under 35 USC 102(b) over Gooch (US 5403262 A) have been fully considered but they are not persuasive. Applicant argues that while the apparatus of Gooch teaches a volume control (34), Gooch does not teach that the volume adjusting feature of the device requires a patient to reset the volume of the treatment signal at the beginning of each treatment session. The limitation "for requiring a patient to reset the volume of the treatment signal at the beginning of each treatment session" is considered to be a statement of intended use of the device. The claim does not recite any structural details pertaining to a mechanism by which the volume control requires resetting by the patient. Therefore, the apparatus of Gooch is fully capable of being used for requiring a patient to reset the volume at any point in time. Resetting the volume before using the device of Gooch could be a personal choice, an instruction

from a doctor to prevent a patient from accidentally damaging their ear by using the device with the volume set on high, or could even be an instruction via the audio output instructing the user to adjust the volume. By merely indicating an intended use of the invention, the Applicant has failed to structurally distinguish the apparatus as claimed from the prior art of record.

Applicant's arguments dated January 12, 2007 on page 9 with respect to claims 27-29, 31, 32, 37 and 38 as rejected under 35 USC 102(b) over Aldeman (US 6041129 A) have been fully considered but they are not persuasive for the same reasons state above with respect to Gooch.

Applicant's arguments on page 10 with respect to claims 1-8, 10, 14-21 and 23 as rejected under 35 USC 103 over Al-Jassim in view of Sony (1995) have been fully considered but they are not persuasive. Applicant argues that this combination does not teach a volume adjusting feature for requiring a patient to reset the volume of the treatment signal. For the reasons given above with respect to Sony, these arguments are not persuasive.

Applicant's arguments on page 11 with respect to claims 27-29, 31 and 32 as rejected under 35 USC 103 over Zoels et al. in view of Rastatter et al. have been fully considered but they are not persuasive. Applicant argues that this combination would not have been obvious to one having ordinary skill in the art at the time of the invention and that as a combination it does not teach a volume adjusting feature for requiring a patient to reset the volume of the treatment signal. However, volume adjustment features on hearing aid devices were commonly known in the art at the time of the

invention and therefore, this combination would have been obvious. For the reasons given above with respect to Sony, the arguments with respect to the volume adjustment feature requiring a patient to reset the volume are not persuasive.

Applicant's arguments on page 11 with respect to claims 27-29, 31-32 and 35-37 as rejected under 35 USC 103 over Topholm have been fully considered but they are not persuasive. Applicant argues while Topholm teaches a volume adjusting feature, it does not teach that the volume adjusting feature is for requiring a patient to reset the volume of the treatment signal. For the reasons given above with respect to Sony, these arguments are not persuasive.

Applicant's arguments on page 10 with respect to claims 9, 11 and 24 as rejected under 35 USC 103 over Sony in view of Wolf et al. have been fully considered but are not fully persuasive. The rejection of claims 9, 11 and 24 as set forth in the Office Action dated September 19, 2006 have been withdrawn. However, claims 11 and 12 are rejected above because identification labels were commonly in use at the time of the invention. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a label having a user identification code with a device similar to that of Sony in order to identify the owner of said device if lost. Furthermore, at the time of the invention manufacturing labels with identification codes were commonly known in the art to be combined with devices and if lost, said label could have been used to identify the owner of a device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.L.

CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700